



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,539	08/16/2006	Klaus Abraham-Fuchs	32860-001074/US	8488

30596 7590 12/09/2010
HARNESSE, DICKEY & PIERCE, P.L.C.
P.O.BOX 8910
RESTON, VA 20195

EXAMINER

WINSTON III, EDWARD B

ART UNIT	PAPER NUMBER
----------	--------------

3686

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

12/09/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

demailroom@hdp.com
siemensgroup@hdp.com
pshaddin@hdp.com

Office Action Summary	Application No. 10/589,539	Applicant(s) ABRAHAM-FUCHS ET AL.	
	Examiner EDWARD WINSTON	Art Unit 3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on June 15, 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The following Office action in response to communications received June 15, 2010. Claim 1 has been amended. Therefore, claims 1-14 are pending and addressed below.
2. Applicant's amendments to the claims are sufficient to overcome the **35 USC § 112 second paragraph** and **35 USC § 102**, rejections set forth in the previous office action dated April 16, 2009.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 3-14 are rejected under 35 U.S.C. 103 (a) as being anticipated by RAO, R., Bharat (WO 03/040878 A2) in view of Barret et al. (US 7,542,911).

CLAIM 1 -

RAO teach(s) a method for selecting and reporting a potential participant for a medical project with selection criteria for patients, said method comprising:

- checking the patient data, with respect to the selection criteria automatically if the determining step determines the patient data has changed; selecting the patient associated with the patient data as a potential participant if the selection criteria are met; and reporting the selected patient as a potential participant. (See at least Abstract, Page 7 || 14-21, Page 8 || 16-24)

Examiner notes for Making Automatic please refer to [In re Venner, 120 USPQ 192 (CCPA 1958) In re Rundell, 9 USPQ 220; It is not 'invention' to broadly provide a mechanical or automatic means to replace manual activity which has accomplished the same result] or [In re Venner, 120 USPQ 192 (CCPA 1958), In re Smith, 73 USPQ 394 ; If a new combination of old elements is to be patentable, the elements must cooperate in such manner as to produce a new, unobvious, and unexpected result. It must amount to an invention.].

Rao does not explicitly teach a method wherein determining if patient data associated with a patient has changed, the patient data being stored in a data processing system and associated with a plurality patient. It would have been obvious to one of ordinary skill in the art at the time of the invention to expand the method of Rao to include Patient Log 30: This field is comprised of one or more log subrecords 30a-30n. Each log subrecord logs any additions, deletions or modifications to any field or sub-record of patient information. Each log subrecord indicates the date of change to the patient information, person or entity making change (e.g., patient or physician), key to record being changed, and change made. All the software programs 12, 14, and 16 that are capable of modifying a patient record 18i would include the capability to automatically write an entry to the log record whenever information in the patient record 18i is modified (see at least Col 3 || 47-55) as taught by Barret et al.. One of ordinary skill in the art at the time of the invention would have been motivated to expand the method of Rao in this way to ensures that no one can change any patient information without such change being recorded in an unalterable record.

CLAIM 2 -

RAO further teach(s) a method as claimed in claim 1,

- wherein verification, with respect to the selection criteria, takes place automatically when the patient data in the data processing system change. (See at least Abstract, Page 2 || 17-

19)

CLAIM 3 AND 9 -

RAO further teach(s) a method as claimed in claim 1,

- wherein, in order to conduct the medical project, an agreement of the participant is needed in which when a patient is selected as a potential participant, the data processing system automatically generates a request asking for the participant's agreement, the request is transmitted (i.e. sent out) to the patient, and in the event of an agreement, the patient is selected as a participant and reported. (See at least Abstract, Page 8 || 16-24)

CLAIM 4 AND 10 -

RAO further teach(s) a method as claimed in claim 3 and 9,

- wherein the selection of a patient as a potential participant takes place during a treatment of the patient for a condition related to the medical project, the request is generated during the treatment and transmitted to the patient, and if the patient agrees, the treatment is continued on him as a participant in accordance with the medical project.
(see at least Page 12 || 7-9 i.e. medical project/ testing a new drug on black males [selection criterion]; Figure 4)

CLAIM 5 and 11 -

RAO further teach(s) a method as claimed in claim 1,

- wherein rules of conduct are assigned to the medical project, and when a patient is selected as a potential participant, the rules of conduct are reported (i.e. details of trail).
(see at least Page 8 || 16-24)

CLAIM 6 and 12-

RAO further teach(s) a method as claimed in claim 5 and 11,

- wherein when a patient is selected as a potential participant, the rules of conduct are assigned to the selected patient (i.e. details of trail). (See at least Abstract, Page 8 || 16-24)

CLAIM 7 and 13-

RAO further teach(s) a method as claimed in claim 5 and 6,

- wherein the rules of conduct are transmitted to a workflow management system. (See at least Page 6 || 20-24; Page 7 || 1-4)

CLAIM 8 and 14 -

RAO further teach(s) a method as claimed in claim 1,

- wherein a clinical study is conducted as the medical project. (See at least Abstract, Page 12 || 7-9)

Response to Arguments

Applicant's arguments, filed on June 15, 2010 with respect to claims 1 in the remarks, have been considered but are moot in view of the new ground(s) of rejection necessitated by the **new limitations added to Claims 1.**

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EDWARD WINSTON whose telephone number is (571)270-7780. The examiner can normally be reached on MONDAY-THURDAY; 9:00AM-6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/E. W./

Examiner, Art Unit 3686
30 November 2010

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686